In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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GEOFF MEAD, as parent and guardian of	*	
minor petitioner, M.M.,	*	
•	*	No. 19-667V
Petitioner,	*	Special Master Christian J.
	*	Moran
V.	*	
	*	Filed: October 3, 2023
SECRETARY OF HEALTH	*	,
AND HUMAN SERVICES,	*	
,	*	
Respondent.	*	
* * * * * * * * * * * * * * * * * * * *	* *	

<u>Patricia A. Finn</u>, Patricia Finn, P.C., Nanuet, NY, for petitioner; <u>Kimberly S. Davey</u>, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING ATTORNEYS' FEES AND COSTS¹

Geoff Mead alleged that a dose of a meningococcal vaccine his son, M.M., received on May 16, 2016, caused him to suffer a neurologic condition known as chronic inflammatory demyelinating polyneuropathy ("CIDP"). Despite Mr. Mead's submission of reports from doctors he retained, his evidence never rose to a minimally competent level and his case was dismissed after an order to show cause was issued. Entitlement Decision, issued May 26, 2022, 2022 WL 2188455.

¹ Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

Mr. Mead now seeks, as permitted by the Vaccine Act, an award of attorneys' fees and costs. The Secretary opposes. Because Mr. Mead has not established a reasonable basis for the claim presented in his petition, he is not eligible for an award of attorneys' fees and costs. Thus, his motion for attorneys' fees and costs is DENIED. Further, Mr. Mead's attorney is ORDERED to return funds her client provided to her.

I. Health and Events in M.M.'s Life²

A. Events Through July 2016

M.M. was born in 2004. His health for the first 12 years of his life appears not to contribute to any neurological problems. He was regularly seen by doctors for eczema. See Exhibits 18A and 18B. He participated in sports.

M.M. attended a routine health visit with his pediatrician on May 16, 2016. Exhibit 4 at 1. The pediatrician, Salvatore Caravella, indicated that his exam was normal. <u>Id.</u> at 3-4. During this visit, M.M. received a dose of the meningococcal vaccine that allegedly harmed him. Exhibit 1. The brand of the meningococcal vaccine is Trumenba.

According to Mr. Mead, within an hour of the vaccination, M.M. started to develop a fever, followed by lethargy and numbness. Pet., filed May 6, 2019, at ¶ 4; see also Exhibit 2 (Mr. Mead's affidavit, dated Apr. 6, 2019) at ¶ 7. The day after vaccination, M.M. returned to the office of his pediatrician where Dr. Eve Meltzer attended to him. M.M. had a fever of 100.2 degrees. Dr. Meltzer recorded that he had a "tingly sensation over [his] body, achiness and a feeling of weakness where he felt it was difficult to grip his pencil in school." Exhibit 1 at 2. Dr. Meltzer's neurologic exam was normal. Id. Dr. Meltzer opined that M.M. was "having a reaction to the [Trumenba] vaccine which should last no more tha[n] 24-36 hours." Id. She advised the family to follow up if symptoms persisted or worsened. Id.

² The section about the events in M.M.'s life and the section about the procedural history are largely taken from the Entitlement Decision.

On May 19, 2016, M.M.'s family brought him to the emergency room at Huntington Hospital. The chief complaint was stiff neck and paresthesia. Exhibit 14 at 111 (call log).

When a doctor in the emergency room (Dr. Kashefsky) saw M.M., the doctor reported that M.M. was found "to not be in distress playing a game on his telephone and freely moving his head and neck." <u>Id.</u> Dr. Kashefsky spoke with Dr. Caravella and told Dr. Caravella about parental fears of Guillain-Barré syndrome ("GBS") post-vaccination. Dr. Caravella referred the family to a neurologist, Dr. Greg Rosenn.

Dr. Rosenn also saw M.M. on May 19, 2016. The family informed Dr. Rosenn that shortly after receiving the meningococcal vaccine, M.M. developed a fever and began complaining of weakness, headache, and numbness and tingling in his hands, feet, and lower extremities. Exhibit 14 at 105. Dr. Rosenn's neurologic exam was "non-focal." <u>Id.</u> at 106. His impression was "reaction to vaccine meningococcal (5/16)." <u>Id.</u> Dr. Rosenn also planned to "rule out polyneuropathy." <u>Id.</u> On May 20, 2016, Dr. Rosenn told Dr. Meltzer that he saw M.M. "yesterday and today with a completely normal neurologic exam and no deficits at all." <u>Id.</u> at 112 (call log).

Dr. Rosenn ordered tests for M.M. An EEG produced normal results. Exhibit 3 at 4 (May 21, 2016). Similarly, an MRI of M.M.'s brain was normal. $\underline{\text{Id.}}$ at 5-6 (May 22, 2016).

Dr. Rosenn reviewed these results as part of an appointment on May 31, 2016. M.M. told Dr. Rosenn that his symptoms had improved, and he did not have headaches any longer. Although his dizziness continued, it had decreased. M.M. also reported that the numbness was intermittent and limited to certain locations. Exhibit 3 at 3. Dr. Rosenn's neurologic exam was normal. Dr. Rosenn assessed M.M. as having "possible polyneuropathy but no objective findings," "possible post viral general malaise resolving," and "headaches resolved." <u>Id.</u> Dr. Rosenn also "cleared [M.M.] to go back to gym and sports." <u>Id.</u>

Nearly one month later, on June 23, 2016, M.M. returned to Dr. Rosenn. M.M. reported that his symptoms had "slowly resolved" over the past 3-4 weeks. Exhibit 14 at 108.

Most of Dr. Rosenn's neurologic exam was normal. The exceptions were that M.M. had difficulty performing "sequential finger thumb opposition," and heel and toe walking provoked "slight dizziness." Exhibit 3 at 1; Exhibit 14 at 109. Dr. Rosenn's impression resembled his previous impressions. Dr. Rosenn stated that M.M. had "1. Reaction to vaccine meningococcal (5/16) 2. Mild polyneuropathy 3. Post viral malaise." Dr. Rosenn added: "The symptoms have resolved." <u>Id.</u> Because the symptoms had resolved, M.M. could return to his usual physical activities without any restrictions and M.M. did not need to follow up. Exhibit 3 at 2; Exhibit 14 at 110.

B. Medical Records from July 2016 Through April 2017

M.M. returned to the doctor whom he was seeing for allergies, Amy Korobow, on September 11, 2016. One complaint was a "severe reaction to the Trumenba vaccine," including "weakness and fatigue." Exhibit 18A at 31. M.M.'s mother stated that his symptoms of atopic dermatitis had worsened after he stopped his allergy injections and requested resuming those injections as soon as possible. <u>Id.</u> Dr. Korobow's review of M.M.'s neurologic system was negative. Id. at 32.

M.M. saw two doctors on November 9, 2016. First, he saw his pediatrician and reported a sore throat. Exhibit 14 at 115.

Also, M.M. returned to Dr. Rosenn. The history included "headaches, dizziness and sensory disturbance possibly related to pneumococcal vaccine." Exhibit 3 at 7.³ Dr. Rosenn noted that M.M. had chronic headaches and was previously diagnosed with polyneuropathy. <u>Id.</u>⁴ In conjunction with this visit, Dr. Rosenn wrote a "To Whom It May Concern" letter, stating M.M. was neurologically cleared to receive allergy shots and the flu vaccine. <u>Id.</u> at 8.

Complaining about eczema and a sore throat, M.M. saw Dr. Meltzer on December 9, 2016. Exhibit 1 at 4. Dr. Meltzer described him as having "a full

³ The reference to "pneumococcal vaccine" appears to be an error as M.M. received a meningococcal vaccine.

⁴ Reading Dr. Rosenn's handwritten notes was sometimes difficult.

body allergic reaction to the environment." Exhibit 14 at 120. She prescribed oral steroids and creams for his eczema. <u>Id.</u> at 122. This visit did not memorialize any neurologic problems.

M.M. had appointments with his allergist, Dr. Korobow, on February 6, 2017 and April 26, 2017. In the earlier appointment, Dr. Korobow recorded that M.M. was "much better and seem[ed] to have recovered from the neurologic reaction he had to the new meningitis vaccine and he [was] still being monitored by neurology." Exhibit 18A at 28. In the latter appointment, M.M. reported an exacerbation of his eczema and swollen eyes after stopping allergy injections. Id. at 25. Dr. Korobow noted that M.M.'s eczema was "out of control." Id. at 27. She recommended consulting M.M.'s neurologist as to whether M.M. could participate in immunotherapy. Dr. Korobow also prescribed oral steroids. Id.

Interspersed with the appointments with Dr. Korobow, M.M. also saw Dr. Rosenn. On December 12, 2016, M.M. complained to Dr. Rosenn about headaches that were "constant [and] daily." Exhibit 3 at 12. Other complaints included dizziness and sensory disturbance. Dr. Rosenn's neurologic exam was normal. Id.

Follow-up appointments with Dr. Rosenn occurred on February 1, 2017 and March 1, 2017. Exhibit 3 at 10-11. The neurologic exams in both appointments were normal. Id.

C. Medical Records from May 2017 Through September 2017

M.M. reported experiencing numbness from his legs to his chest at a visit to the emergency room at Huntington Hospital on May 30, 2017. Exhibit 6 at 2. The history of his present illness included "presumed mild GBS approximately 1 year ago after a meningitis vaccine." <u>Id.</u> at 8. An exam indicated weakness in all four extremities. <u>Id.</u> at 10. He was then transferred to another facility. <u>Id.</u> at 13.

At the second hospital (Cohen Children's Medical Center / Northwell Health), M.M. again presented with "upper extremity and lower extremity weakness and numbness extending to the waist." Exhibit 5 at 3. The previous medical history likewise states that M.M. had "migraines and history of Guillain Barre syndrome-like episode after meningitis vaccine in the fall." <u>Id.</u> An exam revealed that M.M. had normal reflexes. His sensation to light touch was

decreased on both his arms and legs. <u>Id.</u> at 4. M.M. was discharged with a plan to obtain a nerve conduction study ("NCS"). Id.

Dr. Rosenn telephoned Huntington Village Pediatrics to inform Dr. Caravella that M.M. had been seen in two facilities "due to proximal muscle weakness, sensory disturbance [on the] arms and legs and around [the] waist." Exhibit 14 at 137 (May 31, 2017). Dr. Rosenn said that "last year [M.M.] had a 'strange' reaction to Meningitis B vaccine with neuro[logical] [signs and symptoms] but these resolved." <u>Id.</u> Dr. Rosenn wondered "if there is a relationship or if some neuro[logical] issue actually existed that is now emerging again." <u>Id.</u>

Following M.M.'s trips to the hospital, Dr. Rosenn saw M.M. on June 1, 2017. M.M. stated that he had a tingling sensation in his legs that spread to his arms and felt "weak and off balance." Exhibit 3 at 20. The neurologic exam was essentially normal. <u>Id.</u> at 21. To rule out peripheral nerve dysfunction, Dr. Rosenn recommended an electromyography ("EMG") / nerve conduction velocity ("NCV") study. <u>Id.</u> at 22. A note from July 14, 2017 indicates that M.M. did not receive this testing because the family could not find a provider. Exhibit 14 at 143 (Dr. Caravella).

At a follow-up visit with Dr. Rosenn on June 21, 2017, M.M. reported that his numbness and weakness had lessened, and he was having headaches less frequently. Exhibit 3 at 19.

During a well-child visit at Huntington Village Pediatrics, M.M. and his mother stated that M.M. was still having "ongoing neurological issues since receiving [the] [T]rumenba vaccine last year," including a "numbness/burning sensation," "extreme pain to torso when shower[ing]," and "weakness in both legs when he stands too long." Exhibit 14 at 142 (July 14, 2017). The neurologic exam by Dr. Caravella was normal. <u>Id.</u> at 146. Dr. Caravella's impressions included: "extreme exercise intolerance: related to neurological situation post vaccination or ??beginning of an emotional component to this illness." <u>Id.</u> at 148.

Dr. Caravella's July 14, 2017 record reflects some concern about a possible vaccine-induced injury. Dr. Caravella wrote:

Vaccine reaction: unclear but it would seem that based on timeline possible [sic]. Flu like [signs and symptoms including] fever [and] headache day after vaccination, sub[sequently] seen by Dr. Rosen[n], exacerbation of symptoms months later, month after child went to Princeton for a sports tournament, child is known allergic seasonal, foods, etc, has eczema, asthma [-] is this all immunological? Auto immune? I suggested to the father that if SB neuro was not helpful that we should consider NYC [Presbyterian] or Boston Children's. Get evaluations from neurology, allergy/immunology and rheumatology.

Exhibit 14 at 149.

After Dr. Caravella referred M.M. to a dermatologist, M.M. saw Dr. Leonard Kristal on July 25, 2017. Exhibit 14 at 155. Dr. Kristal told Dr. Caravella that M.M.'s "burning skin, severe peeling, [and] paresthesia [we]re all likely related to the extreme eczema . . . and that the present treatments [we]re not addressing the acute nature of the problem." <u>Id.</u> at 154 (call log). Dr. Kristal stated that an autoimmune condition was not likely.

D. Medical Records from October 2017 Through December 2017

M.M. saw Dr. Korobow on October 6, 2017. Exhibit 18A at 22. Dr. Korobow recorded that M.M. "was really under excellent control while on immunotherapy but his eczema has flared and is worse than ever since a few months after stopping treatment." <u>Id.</u> Dr. Korabow added that "[t]herapy was stopped because he had an idiopathic neurologic reaction to [Trumenba] and he has been suffering with severe headaches since that time." <u>Id.</u> Dr. Korobow planned to start immunotherapy. <u>Id.</u> at 24.

M.M. had his first appointment with Dr. Lourdes Bello-Espinosa, a neurologist, on October 18, 2017. M.M.'s parents informed Dr. Bello-Espinosa that M.M. developed numbness and tingling in his hands and feet and lower extremities shortly after a dose of the meningococcal vaccine in May 2016. Exhibit 10 at 3. They also told her that M.M. "has never been symptom free and he had an exacerbation of his symptoms approximately 1 year after . . . in May of

2017 in the setting of a viral infection." <u>Id.</u> Dr. Bello-Espinosa's review of systems indicated numbness and tingling in M.M.'s extremities. <u>Id.</u> at 4. However, her neurologic exam, including a test of his reflexes and strength, was normal. <u>Id.</u> at 6-7. Dr. Bello-Espinosa's impression included "headaches, neuropathy and post vaccination reaction." <u>Id.</u> at 7. She recommended electrodiagnostic testing.

M.M. underwent an EMG/NCV study on November 20, 2017. Exhibit 8 at 1. The doctor who conducted the test, Michael Guido, stated, "This is a normal study. There is no unequivocal evidence of neuropathy at this time." Id. at 3.

Dr. Bello-Espinosa reviewed these results in a follow-up appointment on December 13, 2017. She stated the nerve conduction study "showed decreased amplitude of potential, likely indicative of recovery from his prior injury." Exhibit 9 at 18. Her neurologic exam was normal. <u>Id.</u> at 22.

E. Other Neurologic Records Created in 2018 and 2019⁵

In 2018, M.M. saw Dr. Bello-Espinosa twice. On each occasion, the purpose of the visit was a follow-up for a vaccine reaction. Exhibit 9 at 8 (June 6, 2018); exhibit 21 at 91 (Oct. 15, 2018). On both occasions, his neurologic exam was normal. Exhibit 9 at 11-12; exhibit 21 at 94.

Two more appointments with Dr. Bello-Espinosa happened in 2019. On February 4, 2019, M.M.'s mother asked whether M.M. could stop taking medications, but Dr. Bello-Espinosa wanted a follow-up EMG/NCV before tapering any medications. Exhibit 14 at 214. A follow-up visit was on July 29, 2019, during which M.M. was doing well. <u>Id.</u> at 222.

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⁵ This section omits a discussion of records from M.M.'s allergist and pediatricians.

II. Procedural History

Mr. Mead alleged that the meningococcal vaccine caused his son, M.M., to suffer chronic inflammatory demyelinating polyneuropathy ("CIDP"). Pet., filed May 6, 2019. Mr. Mead periodically filed medical records and other material.

Respondent opposed the award of compensation. Respondent commented that M.M.'s treating doctors did not diagnose him with CIDP, despite several exams within a week of the vaccination. Resp't's Rep., filed Jan. 28, 2020.

Mr. Mead anticipated obtaining a report from an expert. Thus, the undersigned issued Instructions to guide the presentation of opinions. Order, issued Apr. 13, 2020.

Obtaining a report from an expert took a relatively long amount of time. Mr. Mead eventually submitted a report from Dr. Yehuda Shoenfeld on February 2, 2021. Exhibit 27.

As explained in a February 24, 2021 status conference, Dr. Shoenfeld's report was not persuasive. Although the petition claimed M.M. suffered from CIDP, Dr. Shoenfeld did not discuss CIDP very much. Dr. Shoenfeld did not set forth a supported theory by which the meningococcal vaccine can cause CIDP. Another significant omission was that Dr. Shoenfeld did not explain timing at all. Accordingly, Mr. Mead was directed to obtain a supplemental report from Dr. Shoenfeld. Order, issued Feb. 24, 2021.

Mr. Mead did not immediately file a report from Dr. Shoenfeld. Instead, on March 15, 2021, Mr. Mead presented a report from a neurologist, Dr. Avinoam Shuper. Exhibit 55. Dr. Shuper opined that M.M. suffered from "inflammatory neuropathy which resembled GBS in the beginning but progressed to CIDP." <u>Id.</u> at 14. Thereafter, on May 18, 2021, Mr. Mead filed a one-sentence report from Dr. Shoenfeld. Exhibit 73 (stating Dr. Shoenfeld "fully agree[d]" with Dr. Shuper's diagnosis).

A status conference was held on August 24, 2021, to discuss Mr. Mead's expert reports. The undersigned discussed with Mr. Mead's counsel that Dr. Shoenfeld did not appear to be helpful to Mr. Mead in that he did not adequately address the relevant issues outlined in the expert instructions and the previous guidance. Specifically, he appeared not to address timing. Mr. Mead's counsel

requested 60 days to consult with Dr. Shoenfeld or potentially to speak with another neurologist or other expert and submit a supplemental expert report. Order, issued Aug. 24, 2021.

Mr. Mead submitted another report from Dr. Shoenfeld on October 14, 2021. Exhibit 74. This two-page report summarized information presented in all the expert reports. Nevertheless, Dr. Shoenfeld's opinion remained unpersuasive.

An Order to Show Cause was issued on October 15, 2021. This order explained that Mr. Mead had not presented a minimally competent case. Thus, Mr. Mead was allowed a final opportunity either to cure the deficiencies or to have his case dismissed.

Mr. Mead filed a five-page response to the Order to Show Cause on December 14, 2021. Mr. Mead submitted additional evidence in conjunction with this response on December 14, 2021, and on January 3, 2022. The Secretary provided comments on Mr. Mead's response on February 3, 2022. This document is fourteen pages. Mr. Mead submitted a reply, which is six pages, on March 15, 2022. With this reply, Mr. Mead submitted seven additional exhibits, including another report from Dr. Shoenfeld.⁶

Mr. Mead's case was dismissed. <u>Entitlement Decision</u>. The basis was "the doctors whom Mr. Mead retained have not established that CIDP is an appropriate diagnosis for M.M. Even if M.M. suffered from CIDP, Mr. Mead's experts have not explained how M.M. could experience the first symptoms of CIDP within one hour of the vaccination." 2022 WL 2188455 at *1.

Mr. Mead requested an award of his attorneys' fees and costs. Pet'r's Mot., filed Dec. 15, 2022. This motion did not set forth any argument as to why Mr.

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⁶ Given that the Order to Show Cause identified the critical issues in the case and the Secretary's February 3, 2022 comments about Mr. Mead's response to the Order to Show Cause did not include any new evidence, Mr. Mead's introduction of new evidence in conjunction with a reply brief is a questionable practice. Mr. Mead did not explain why any of the material submitted on March 15, 2022 could not have been submitted with his initial response to the Order to Show Cause on December 14, 2021. Nevertheless, all evidence has been considered.

Mead was eligible for an award of attorneys' fees and costs. In addition to seeking the fees and costs his counsel incurred, Mr. Mead sought reimbursement of expenses that he incurred personally. Exhibit 94 (General Order #9 statement with supporting documentation).

The Secretary opposed any award of attorneys' fees and costs. Resp't's Opp'n., filed Dec. 29, 2022. The Secretary contended that: "Petitioner has not set forth sufficient objective evidence that M.M. had CIDP, the injury alleged, or that the vaccination could have caused in fact his alleged condition." <u>Id.</u> at 6. The Secretary further maintained that "the evidence petitioner presented not only falls short of a preponderance, but it also falls short of the evidence that would be required to support reasonable basis – and indeed, amounts to no more than a scintilla, the absolute minimum required to survive a reasonable basis challenge." Id.

Mr. Mead argued that he satisfied the reasonable basis standard. Pet'r's Resp., filed Jan. 5, 2023. He argued that objective evidence supported a claim of CIDP. <u>Id.</u> at 2-3. He also stated that "Petitioner's experts did indeed address the timing issue, an essential element to establish causation under <u>Althen</u>, and thus, had a reasonable basis to continue the claim." <u>Id.</u> at 5.

Because Mr. Mead presented the arguments regarding reasonable basis for the first time in his January 5, 2023 response, the Secretary was afforded an opportunity to address them. Order, issued Jan. 10, 2023. The Secretary did so in a Supplemental Response, filed Feb. 1, 2023. The Secretary continued to challenge the reasonable basis for the assertion that M.M. suffered from CIDP. <u>Id.</u> at 2-3. The Secretary also pointed out perceived deficiencies in Mr. Mead's argument: "Remarkably, in his Reply, petitioner asserts that his experts 'did indeed address the timing issue, an essential element to establish causation under <u>Althen</u>...' Reply at 5. Notably, petitioner does not cite to his expert reports in making this assertion, perhaps because it is objectively false." <u>Id.</u> at 4.

Mr. Mead did not file anything in response to the Secretary's supplemental brief. The motion for attorneys' fees and costs is, therefore, ready for adjudication.

III. Standards for Adjudication

Petitioners who have not been awarded compensation (like Mr. Mead here) are eligible for an award of attorneys' fees and costs when "the petition was brought in good faith and there was a reasonable basis for the claim." 42 U.S.C. § 300aa-15(e)(1). As the Federal Circuit has stated, "good faith" and "reasonable basis" are two separate elements that must be met for a petitioner to be eligible for attorneys' fees and costs. Simmons v. Sec'y of Health & Hum. Servs., 875 F.3d 632, 635 (Fed. Cir. 2017). Here, the Secretary has not raised a challenge to Mr. Mead's good faith. Thus, the disputed issue is reasonable basis.

In <u>Cottingham v. Sec'y of Health & Hum. Servs.</u>, the Federal Circuit stated that the evidentiary burden for meeting the reasonable basis standard "is lower than the preponderant evidence standard." 971 F.3d 1337, 1346 (Fed. Cir. 2020). Something "more than a mere scintilla" might establish the reasonable basis standard. <u>Id.</u> at 1356. Petitioners meet their evidentiary burden with "objective evidence." <u>Id.</u> at 1344. In categorizing medical records as objective evidence, the Federal Circuit stated, "[m]edical records can support causation even where the records provide only circumstantial evidence of causation." <u>Id.</u> at 1346. Finally, the Federal Circuit in <u>Cottingham</u> specified that "we make no determination on the weight of the objective evidence in the record or whether that evidence establishes reasonable basis, for these are factual findings for the Special Master and not this court." <u>Id.</u> at 1347.

In its most recent opinion regarding the reasonable basis standard, the Federal Circuit stated that medical records, affidavits, and sworn testimony all constitute objective evidence that could support reasonable basis. <u>James-Cornelius v. Sec'y of Health & Hum. Servs.</u>, 984 F.3d 1374, 1379-81 (Fed. Cir. 2021). The Federal Circuit further clarified that "absence of an express medical opinion on causation is not necessarily dispositive of whether a claim has reasonable basis, especially when the case is in its early stages and counsel may not have had the opportunity to retain qualified experts." <u>Id.</u> at 1379 (citing <u>Cottingham</u>, 971 F.3d at 1346). These two most recent decisions guide the analysis regarding what types of evidence constitute objective evidence of reasonable basis, as originally articulated in <u>Simmons</u>, though the ultimate weighing of such evidence is left up to the special master.

IV. Analysis

Mr. Mead has not carried his burden of presenting beyond a scintilla of evidence on either of the critical issues---diagnosis and timing. These are addressed below.⁷

A. Diagnosis

In <u>Broekelschen v. Secretary of Health & Human Services</u>, 618 F.3d 1339, 1346 (Fed. Cir. 2010), the Federal Circuit recognized that in some circumstances, the special master may "first determine which injury was best supported by the evidence in the record before applying the <u>Althen</u> test." Here, Mr. Mead has not established that M.M. suffered from the condition he alleges the meningococcal vaccine caused.

Identifying the condition that the vaccine allegedly caused is a critical step because the Vaccine Act requires a special master to find "there was a reasonable basis for the claim for which the petition was brought." 42 U.S.C. § 300aa–15(e). Mr. Mead's claim is that the meningococcal vaccination was the cause-in-fact of M.M.'s "chronic inflammatory demyelinating polyneuritis." Pet. ¶ 23. Thus, the evaluation for reasonable basis must focus on CIDP.

The focus on CIDP necessarily pushes other potential conditions to the background. Thus, although M.M. may have developed a fever after receiving the meningococcal vaccine and this fever may have persisted for two days, Mr. Mead's petition does not seek compensation for this immediate reaction by itself. Indeed, the brevity of any fever, lethargy, and numbness was not of sufficient duration to make M.M. eligible for compensation. See 42 U.S.C. § 300aa—11(c)(1)(D) (setting forth a severity requirement). Any fever, lethargy, and numbness might affect the analysis to the extent that they are consistent with or symptomatic of the condition allegedly caused by the vaccine, which is CIDP. Thus, Dr. Melzer's May 17, 2016 statement that M.M. "is having a reaction to the

⁷ Mr. Mead argues that he has fulfilled the first <u>Althen</u> prong. Pet'r's Reply at 8-10. However, a lack of proof on <u>Althen</u> prong one was not the basis of the Entitlement Decision.

[meningococcal] vaccine," Exhibit 1 at 2, is not evidence that M.M. was suffering from CIDP.

Beyond Dr. Melzer's statement, Mr. Mead identifies four points of objective evidence to support the allegation that M.M. suffered from CIDP. These are: Dr. Rosenn's June 28, 2016 record; a statement from a nurse, Ms. Russo; a statement from Dr. Bello-Espinosa on October 18, 2017; and the report from Dr. Shuper. Pet'r's Reply at 1-4. While the Entitlement Decision evaluated this evidence to see whether the evidence, taken as a whole, preponderated in Mr. Mead's favor, the question now pending is whether the evidence, taken as a whole, constitutes a reasonable basis in support of the allegation that M.M. suffered from CIDP.

Even at the less demanding level of proof, the evidence regarding diagnosis does not rise to the level to support reasonable basis for the claim that M.M. suffered from CIDP. On first glance, Dr. Rosenn's June 28, 2016 record may be, perhaps, most supportive of the claim that M.M. suffered from CIDP. In that record from approximately one month after the vaccination, Dr. Rosenn's impression included "Mild polyneuropathy." Exhibit 3 at 1. However, in the exact same record, Dr. Rosenn also wrote "possible polyneuropathy but no objective findings." Id. at 3. As the Secretary points out, although Dr. Rosenn saw M.M. multiple times after the vaccination, Dr. Rosenn "did not diagnose him with CIDP, undercutting petitioner's assertion that a reasonable basis existed for filing this claim." Resp't's Opp'n. at 7, citing Exhibit 3 at 1, 3, 8, 10, 12, 19; Exhibit 5 at 11; Exhibit 10 at 3-7. Mr. Mead did not address these subsequent visits in which Dr. Rosenn, a treating neurologist, did not diagnosis M.M. with CIDP.

The second piece of potentially supportive evidence is the statement from Nurse Russo. On May 30, 2017, she wrote M.M. had "presumed mild GBS approximately 1 year ago after a meningitis vaccine." Exhibit 6 at 8. However, Nurse Russo did not diagnose M.M. with Guillain-Barré syndrome or CIDP. Nurse Russo simply memorialized the history given to her by M.M. and his family. Mr. Mead has not adequately explained how a history that is not consistent with medical records created during the event in question can supply a reasonable basis.

The third piece of potentially supportive evidence for the diagnosis of CIDP is Dr. Bello-Espinosa's impression that M.M. had "neuropathy and post

vaccination reaction." Exhibit 10 at 12 (Oct. 18, 2017). This statement certainly constitutes some evidence supporting the petition's allegation that M.M. suffered from CIDP. However, the value of this evidence is undermined by other information Dr. Bello-Espinosa generated. For example, Dr. Bello-Espinosa ordered an EMG/NCS study and the results were normal. Exhibit 8 at 3. Dr. Bello-Espinosa reviewed these results in a follow-up appointment on December 13, 2017 and her neurologic exam was normal. Exhibit 9 at 22.

The fourth and final piece of potentially supportive evidence is the report from a doctor whom Mr. Mead retained to provide an opinion, Dr. Shuper. ⁹ Dr. Shuper wrote that M.M. suffered from "inflammatory neuropathy which resembled GBS in the beginning but progressed to CIDP." Exhibit 55 at 14. This report, too, gives some support to the petition's claim that M.M. suffered from CIDP. However, Dr. Shuper failed to engage, in any meaningful way, with the normal neurologic exams by Doctors Rosenn and Bello-Espinosa. Dr. Shuper similarly did not adequately explain how the normal EMG/NCS study fits with his diagnosis. See Exhibit 55. Thus, this case presents a rare example in which an expert's report does not carry a petitioner's burden regarding reasonable basis. For other examples, see Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 (Fed. Cir. 1994) ("Congress must not have intended that every claimant, whether being compensated or not under the Vaccine Act, collect attorney fees and costs by merely having an expert state an unsupported opinion"); Woods v. Sec'y of Health & Hum. Servs., 105 Fed. Cl. 148, 153 (2012) ("expert testimony in and of itself does not determine reasonableness' where that testimony is uncorroborated or contradicted by other facts") (quoting Murphy v. Sec'y of Dep't of Health & Hum. Servs., 30 Fed. Cl. 60, 62 (1993), aff'd, 48 F.3d 1236 (Fed. Cir. 1995)); Hoffman v.

⁸ Mr. Mead cites a different record from October 17, 2017, one found in Exhibit 7 at page 3. Pet'r's Reply at 3. However, the material in Exhibit 10 cited in the decision provides a superior amount of context and information.

⁹ Because Dr. Shuper is a neurologist, Dr. Shuper's opinion regarding the appropriate neurologic condition is more valuable than an opinion from Dr. Shoenfeld. In any event, Dr. Shoenfeld did not present any minimally persuasive opinion that M.M. suffered from CIDP and Mr. Mead has not advanced Dr. Shoenfeld's opinion regarding diagnosis.

<u>Sec'y of Health & Hum. Servs.</u>, No. 16-1122V, 2023 WL 3092668, at *21-22 (Fed. Cl. Spec. Mstr. Mar. 29, 2023).

In defending the claim that M.M. suffered from CIDP, Mr. Mead takes comments out of context. For example, Dr. Rosenn's proposal that M.M. suffers from "mild neuropathy" was followed by Dr. Rosenn's finding that any polyneuropathy lacks "objective findings." Exhibit 3 at 1-3. But, special masters are required to base outcomes on the record as a whole. 42 U.S.C. § 300aa–13(a). The record, as a whole, does not weigh in favor of finding that reasonable basis supported the allegation that M.M. suffered from CIDP. (Again, the reasonable basis standard is lower than the preponderance of the evidence standard).

B. Timing

In opposing an award of reasonable basis, the Secretary did not rest on solely on the lack of support for the alleged diagnosis. The Secretary also argued that Mr. Mead's evidence regarding timing was lacking:

Moreover, ... the objective evidence in M.M.'s medical records demonstrates that the onset of the alleged condition occurred within one hour of vaccination, which is simply too fast to establish vaccine causation of a demyelinating condition via molecular mimicry pursuant to the third prong of <u>Althen</u>. Indeed, petitioner, despite multiple opportunities, failed entirely to present an expert opinion addressing how an interval of just one hour is appropriate for a causation theory based upon molecular mimicry.

Resp't's Opp'n. at 8.

Mr. Mead attempted to answer this argument. He asserted: "Petitioner's experts did indeed address the timing issue, an essential element to establish causation under Althen, and thus, had a reasonable basis to continue the claim." Pet'r's Reply at 5.

The Secretary accurately commented that "petitioner does not cite to his expert reports in making this assertion." Resp't's Supp'l Resp. at 4. Given that a

basis for the dismissal was a lack of support for timing, Mr. Mead was aware that evidence regarding timing would affect the outcome on reasonable basis.

The undersigned has not identified any report in which a doctor retained by Mr. Mead addressed timing in a way that fit the allegation of Mr. Mead's case. Thus, the undersigned is concerned about the accuracy of the representation made by Mr. Mead's attorney. Regardless of this concern about counsel's conduct, the question of reasonable basis turns on the evidence.

In Dr. Shoenfeld's report, Dr. Shoenfeld asserted that M.M.'s "adverse reaction started immediately after the vaccine, entailing pains, swelling, and neurological symptoms." Exhibit 74 at 1. Dr. Shoenfeld continued: "In a reasonable period of time following the vaccine he developed a clinical picture of polyneuropathy (GBS, CIDP)." <u>Id.</u> However, Dr. Shoenfeld provides no information defining a "reasonable period of time." His opinion appears to be entirely conclusory. Dr. Shoenfeld's opinion regarding timing is an "unsupported opinion" that does not automatically support a finding of reasonable basis. <u>See</u> Perreira, 33 F.3d at 1377.

Consequently, there is a gap in Mr. Mead's evidence. He has not presented any evidence to support a finding that a vaccine could induce a molecular mimicry reaction manifesting as CIDP in one hour.

The (lack of) evidence regarding timing differs from the evidence regarding diagnosis. For diagnosis, some slight evidence supports a proposition that M.M. suffered from CIDP. The favorable evidence is vastly outweighed by evidence against this proposition.

However, for timing, there is no meaningfully valuable evidence. This lack of evidence on a portion of a petitioner's case justifies a finding that the case lacked reasonable basis. Accordingly, an award of neither attorneys' fees nor costs can be made.

V. Return of Money to Petitioner

The Vaccine Act provides: "No attorney may charge any fee for services in connection with a petition filed under section 300aa-11 of this title which is addition to any amount awarded as compensation by the special master or court under paragraph (1)." 42 U.S.C. § 300aa–15(e)(3). The phrase "fee for services"

includes items such as "filing fees [and] expert witness reimbursement." <u>Beck v. Sec'y of Health & Hum. Servs.</u>, 924 F.2d 1029, 1032 (Fed. Cir. 1991).

Via the present decision, the undersigned has determined that the appropriate amount of attorneys' fees and costs is zero. However, Mr. Mead's counsel has collected \$2,400 from him. Exhibit 94.

The remedy for this overcharge is for Mr. Mead's attorney to refund the money she has received from Mr. Mead. See K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2017 WL 4385751, at *5-6 (Fed. Cl. Spec. Mstr. Oct. 3, 2017) (requiring reimbursement from a law firm to a client). Accordingly, Mr. Mead's attorney is ORDERED to file a status report confirming she has reimbursed Mr. Mead \$2,400.00 within 45 days of this decision.

VI. Conclusion

Mr. Mead has not established a reasonable basis to support his petition's claim that the meningococcal vaccine caused M.M. to develop CIDP within one hour. Without a showing of reasonable basis, M.M. cannot be awarded his attorneys' fees and costs. Thus, his motion for attorneys' fees and costs is DENIED.

- 1. The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. 10
- 2. Within 45 days, Mr. Mead's attorney is ORDERED to file a status report, confirming she has reimbursed Mr. Mead with the \$2,400.00, which she collected from him excessively.

IT IS SO ORDERED.

s/Christian J. MoranChristian J. MoranSpecial Master

¹⁰ Information regarding the content and deadline for a motion for review is available in the Vaccine Rules posted to the Court's website.